

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Joseph C. Eder and Alejandro Berenstein
Application No.:	10/063315
Filed:	April 10, 2002
For:	Hybrid Stent
Examiner:	Ryan J. Severson
Group Art Unit:	3731

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: S63.2B-10039-US01

APPEAL BRIEF

This is an Appeal Brief for the above-identified application. A Notice of Appeal was filed in this case on November 30, 2009.

The Commissioner is authorized to charge Deposit Account No. 22-0350 for any other fees which may be due with this Appeal.

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(i) Real Party in Interest

This Application is assigned to Boston Scientific Scimed, Inc. (formerly Scimed Life Systems, Inc.), One Scimed Place, Maple Grove, Minnesota 55311-1566, a Minnesota Corporation and a subsidiary of Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts 01760-1537, a Delaware Corporation.

(ii) Related Appeals and Interferences

None.

(iii) Status of Claims

Claims 38-41 and 43-55 are pending in this application, stand finally rejected, and are the subject of this appeal. Claims 1-37 and 42 have been canceled.

(iv) Status of Amendments

In response to a Final Office Action mailed on **July 30, 2009**, Applicants presented arguments to overcome the Office Action's rejections of pending claims 38-41 and 43-55 under 35 USC § 103(a). No Amendments were presented. In response to Applicants' arguments, in an Advisory Action dated **November 9, 2009**, the Examiner maintained the rejection of claims 38-41 and 43-55.

On January 14, 2010, Applicants submitted an Amendment after the filing of a Notice of Appeal pursuant to MPEP § 1206(I)(C) in an effort to present rejected claims in better form for consideration on appeal. Specifically, claim 43 was amended to include the word "end", thereby referencing the "first and second end segments" of claim 41, from which claim 43 depends. Claim 46 was amended to remove an extra comma.

On Monday, February 1, 2010, Applicants' Representatives received a telephone call from Examiner Severson indicating that the above Amendments had been entered.

(v) **Summary of Claimed Subject Matter**

Independent claim 38 recites a stent 10 having a longitudinal axis 301 comprising a plurality of segments 90, 100. *See, e.g.*, paragraph [0041], figures 1A, 3, and 6A, below. The stent 10 includes at least one coil segment 100 connected to at least one serpentine segment 90, 305. *See, e.g.*, paragraph [0045] and figure 3. The at least one serpentine segment 90, 305 forms an annular ring about the longitudinal axis 301 of the stent 10. *See, e.g.*, figure 3. The at least one coil segment 100 has curved portions that extend at least 90 degrees about the longitudinal axis 301. Adjacent portions which are aligned in a circumferential direction and longitudinally offset from one another have a substantially constant longitudinal distance between each other. *See, e.g.*, paragraph [0051] and figure 1A. Each of the at least one coil segments 100 extends along a greater longitudinal distance than each of the at least one serpentine segments 90, 305. *See, e.g.*, figure 1A. Either the coil segment 100 is balloon expandable and not self-expanding and the serpentine segment 90, 305 is self-expanding and not balloon expandable, or the coil segment 100 is self-expanding and not balloon expandable and the serpentine segment 90, 305 is balloon expandable and not self-expanding. *See, e.g.*, paragraph [0011].

FIG. 1A

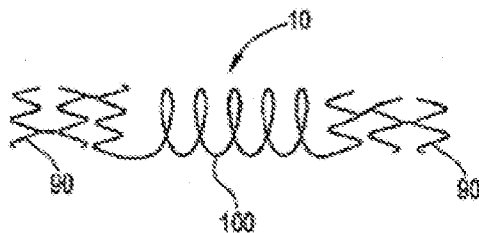


FIG. 6B

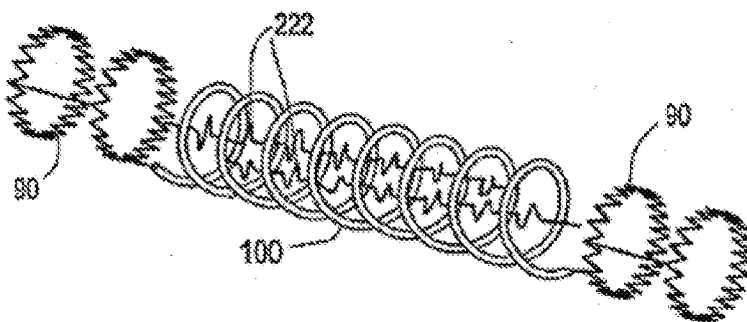
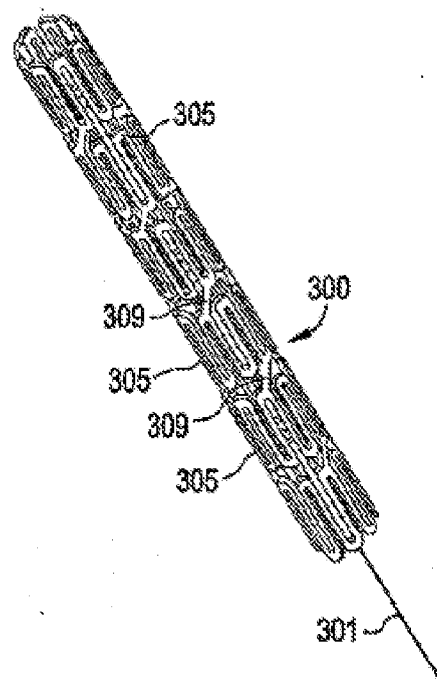


FIG. 3



Independent claim 46 recites a stent 10 comprising a coil segment 100 and a tubular, serpentine segment 90, 305. *See, e.g.*, paragraphs [0041] and [0045]. The coil segment 100 is longer than the tubular serpentine segment 90, 305 in a longitudinal direction. *See, e.g.*, figure 1A. The coil segment 100 has curved portions that extend at least 90 degrees about the longitudinal axis 301. Adjacent portions which are aligned in a circumferential direction and longitudinally offset from one another have a substantially constant distance between each other. *See, e.g.*, paragraph [0051] and figure 1A. Either the coil segment 100 is balloon expandable and not self-expanding and the serpentine segment 90, 305 is self-expanding and not balloon expandable, or the coil segment 100 is self-expanding and not balloon expandable and the serpentine segment is balloon expandable and not self-expanding. *See, e.g.*, paragraph [0011].

Dependent claim 48 recites, “[t]he stent 10 of claim 46 wherein the tubular, serpentine segment 90, 305 is self-expandable.” *See, e.g.*, paragraph [0045].

Dependent claim 55 recites, “[t]he stent 10 of claim 38, wherein at least one coil segment 100 is expandable by balloon-expansion and at least one serpentine segment 90, 305 is expandable by self-expansion. *See e.g.*, paragraphs [0041] and [0045].

(vi) Grounds of Rejection to be Reviewed on Appeal

Issue 1: Did the Examiner err in rejecting claims 38-41, 44, 46-49, and 51-55 under 35 USC § 103(a) over Imran (US 5,817,126) in view of Vonesh (US 6,336,937) and Hojeibane (US 5,911,732)?

Issue 2: Did the Examiner err in rejecting claims 43, 45, and 50 under 35 USC § 103(a) over Imran in view of Vonesh and Hojeibane in further view of Klein (US 5,593,442)?

(vii) Argument

Issue 1: The combination of Imran (US 5,817,126) in view of Vonesh (US 6,336,937) and Hojeibane (US 5,911,732) does not render claims 38-41, 44, 46-49, and 51-55 obvious under 35 USC § 103(a).

The rejections asserted by the Examiner under 35 USC § 103(a) are traversed because the applied references do not teach or suggest the subject matter of independent claims 38 or 46. With respect to claim 38, none of Imran, Vonesh, or Hojeibane, whether considered individually or in combination, teaches or suggests:

[a] stent having . . . at least one coil segment connected to at least one serpentine segment . . . , wherein either the coil segment is balloon expandable and not self-expanding and the serpentine segment is self-expanding and not balloon expandable, or the coil segment is self-expanding and not balloon expandable and the serpentine segment is balloon expandable and not self-expanding.

With respect to claim 46, none of Imran, Vonesh, or Hojeibane, whether considered individually or in combination, teaches or suggests:

[a] stent comprising a coil segment and a tubular, serpentine segment . . . , wherein either the coil segment is balloon expandable and not self-expanding and the serpentine segment is self-expanding and not balloon expandable, or the coil segment is self-expanding and not balloon expandable and the serpentine segment is balloon expandable and not self-expanding.

Consequently, Applicants request that the Board reverse the Examiner's rejections.

Independent claim 38

In rejecting claim 38 over Imran in view of Vonesh and Hojeibane, at page 2, paragraph 2 of the Final Office Action, the Examiner asserts:

Imran discloses a stent (see figure 1) having a coil segment (60) and serpentine segments (20 and 40). . . . However, Imran does not disclose one segment being self-expanding and the other segment being balloon expanding. . . . Vonesh et al. . . . teach a stent [that] may have some sections balloon expanding (56) and the adjacent segments self expanding (59, see figures 7 and 8) to create a stent where consistent performance along the length is not desired (see also column 11, lines 47-59 and particularly lines 54-59).

As shown below in figure 1, Imran discloses “a compound stent . . . having first and second end segments and an intermediate segment adjoining the first and second end segments, the first and second end segments being formed of slotted metal . . . , the intermediate segment being formed of a braided material” Abstract of Imran.

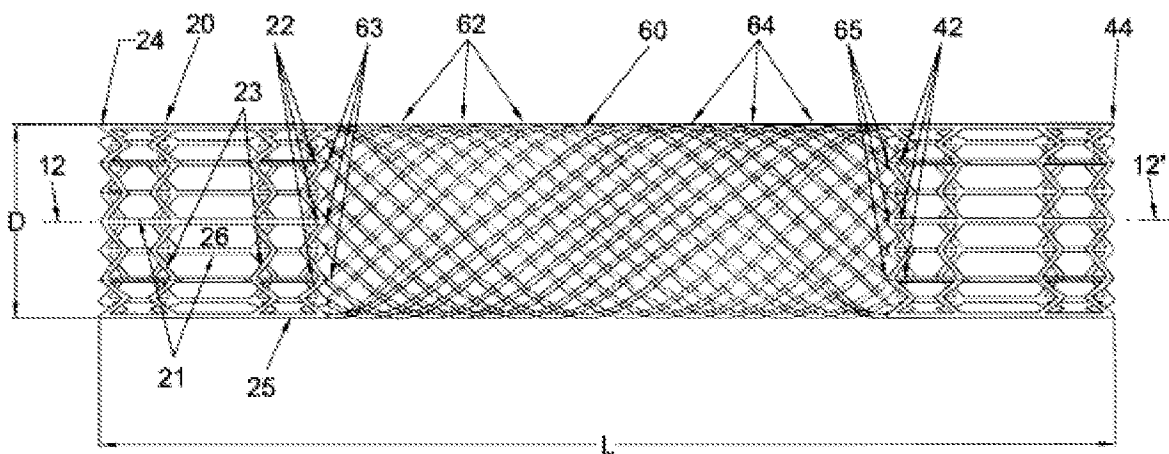
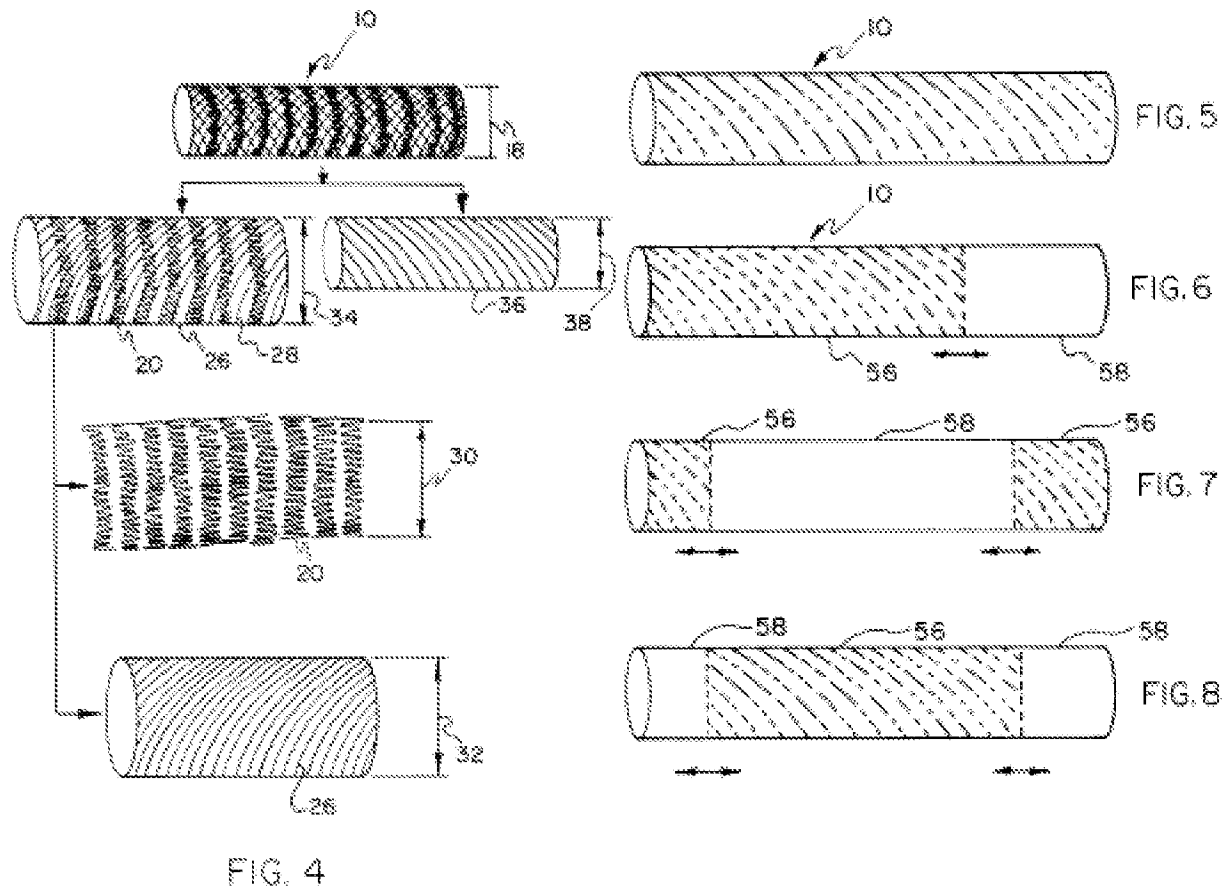


Fig. 1

As depicted in figure 4, below, Vonesh discloses a “multi-stage expandable stent-graft.” Title of Vonesh. Vonesh further discloses a “device 10 [that] begins by attaching together a self expanding stent frame element 20 to an auxiliary sleeve (or “graft”) element 26 to form a first component part 28.” Column 8, lines 62-64. At column 9, lines 9-11, Vonesh states, “[t]he stent frame 20 is preferably attached . . . to the graft element 26.” And, at column 9, lines 34-36, Vonesh discloses “[i]n addition to isolating the stent frame 20, the graft element 26 can also serve to limit the ultimate extent of expansion of the device 10.” Finally, Vonesh discloses, “[i]n order to then cause the device to establish a second dimension 18 . . . , a distensible sleeve element 36 is employed.” Column 9, lines 57-59.



The Examiner's reliance on Vonesh is misplaced. Vonesh does not teach "a stent [that] may have some sections balloon expanding (56) and the adjacent segments self expanding," as asserted by the Examiner. Rather, the underlying stent of Vonesh is self-expanding.

The relied upon devices shown in figures 7 and 8 (above) of Vonesh and described at column 11, lines 49-50, having "self-expanding and balloon distensible section 56 and a section 58 that is self-expanding only," are formed of a combination of a stent frame 20, a graft element 26, and a distensible sleeve element 36. To exemplify, Vonesh states, "[t]he self-expanding stent is attached to a balloon distensible graft component . . . and is prevented from expanded by the graft component or integral constraining lamina" Column 3, lines 24-28. The expanding nature (self-expanding, balloon expanding) of the device of Vonesh, illustrated by hatching in figs. 5-8, is a function of the presence or absence of covering element(s) along the relevant region of the graft and is independent of the configuration of the stent frame 20.

In contrast, Applicants' claim 38 is directed to:

A stent . . . including at least one coil segment connected to at least one serpentine segment . . . , wherein either the coil segment is balloon expandable and not self-expanding and the serpentine segment is self-expanding and not balloon expandable, or the coil segment is self-expanding and not balloon expandable and the serpentine segment is balloon expandable and not self-expanding. (*Emphasis added*).

Claim 38 recites that a particular segment of the stent is balloon expandable while another segment is self-expanding, and these particular segments (balloon expandable or self-expanding) coincide with the structure of the segment – coil or serpentine. Moreover, the expanding nature (balloon expanding or self-expanding) of the coil segment is different than that of the serpentine segment. This difference may, for example, be due to the material used to form the particular segment. Applicants' Specification at Paragraph [0045] (“Where self-expanding segments are used, the self-expanding segments may be made of shape memory materials in order to self-expand . . .”).

As noted above, however, the balloon expandable regions of Vonesh require the presence of the sleeve element(s). Thus, if one, for the sake of argument only, were to combine Imran and Vonesh as proposed, the resulting device would be a combination stent and sleeve. The nature of the underlying Imran stent would not be altered. Consequently, the combination of Imran and Vonesh does not teach or suggest the subject matter of Applicants' independent claim 38.

Moreover, Vonesh does not include any indication that would suggest to one of ordinary skill to selectively apply a sleeve element 36 in conjunction with a particular underlying stent structure. However, even if the sleeve element 36 of Vonesh were added to the structure of Imran, this modification would not change the underlying stent structure of the stent of Imran.

Therefore, Imran in view of Vonesh does not teach or suggest a “coil segment [that] is balloon expandable and not self-expanding and the serpentine segment [that] is self-expanding and not balloon expandable, or the coil segment [that] is self-expanding and not balloon expandable and the serpentine segment [that] is balloon expandable and not self-expanding.”

In addition, Hojeibane does not cure the deficiencies of Imran and Vonesh. Hojeibane discloses a “stent 270 . . . [which] contains a spiral connector “S” between a series of cell type stents 271, 272.” Column 7, lines 34-36. Figure 3 of Hojeibane is provided below for reference.

FIG. 3



As discussed above, the Examiner’s rejection does not include any indication that particular stent segments of the modified device are coordinated with sleeve element(s) 36 of Vonesh. However, even if the sleeve element(s) 36 were coordinated with particular stent segments in the modified device, Imran, Vonesh, and Hojeibane still would not teach or suggest what is claimed in claim 38. Adding the sleeve element 36 of Vonesh would not change the underlying characteristics of the stent to make it self-expanding or balloon expandable, as is claimed. Consequently, the Examiner’s proposed combination fails to teach or suggest a stent as is claimed in independent claim 38 and Applicants request that the Board reverse the Examiner’s rejection.

Dependent claims 39-41, 44, and 54

Dependent claims 39-41, 44, 54, and 55 depend either directly or indirectly from independent claim 38. These claims are therefore patentable for at least the reasons discussed with respect to independent claim 38. Consequently, Applicants request that the Board reverse the Examiner’s rejection of dependent claims 39-41, 44, and 54.

Dependent claim 55

Dependent claim 55 depends from independent claim 38, and recites, “[t]he stent of claim 38, wherein at least one coil segment is expandable by balloon-expansion and at least one serpentine segment is expandable by self-expansion.”

Contrary to the Examiner's proposal to employ the coil segment as disclosed in Hojeibane with the modified stent-graft of Imran/Vonesh, one of ordinary skill in the art would not be motivated to use the coil segment of Hojeibane with the balloon-expandable sleeve element 36 of Vonesh.

Hojeibane discloses:

Stent 70, 170, 270 of the type previously described in connection with FIGS. 1, 2, and 3 are shown, and the tubular shaped members 71 of grafts, or prostheses, 170 have a biologically inert coating placed upon wall surfaces 74 of tubular shaped members 71. . . . The coating should be thin and highly elastic so as not to interfere with the desired expansion of the stent. Column 9, lines 19-27 (*emphasis added*).

Thus, the coil segments of Hojeibane are designed such that the performance of stent is not inhibited by the coating. *Id.* And, any coating applied over the coil-segments of Hojeibane is to be "highly elastic." In contrast, the stent-graft of Vonesh uses "sleeve element 36 [which] will resist any further expansion of the device 10 beyond this second dimension 18" Column 10, lines 31-33; *see also* figure 2 of Vonesh.

As a result, one of ordinary skill in the art would not combine the coil segment of Hojeibane with the modified stent-graft of Imran/Vonesh. The stent of Hojeibane, designed to be used with a thin and highly elastic coating that does "not interfere with the desired expansion of the stent," would not be used with the sleeve element 36 of Vonesh, which limits expansion of the stent. *See* MPEP § 2143.01(V) ("If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." (citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984))).

In light of the foregoing, Applicants request that the Board reverse the Examiner's rejection of dependent claim 55 for this additional reason.

Independent claim 46

Independent claim 46 recites, in-part, "wherein either the coil segment is balloon expandable and not self-expanding and the serpentine segment is self-expanding and not balloon

expandable, or the coil segment is self-expanding and not balloon expandable and the serpentine segment is balloon expandable and not self-expanding.”

Independent claim 46 is patentable for the same reasons discussed above with respect to independent claim 38 and Applicants request that the Board reverse the Examiner’s rejection of independent claim 46.

Dependent claims 47, 49, and 51-53

Dependent claims 47, 49, and 51-53 depend either directly or indirectly from independent claim 46. These claims are therefore patentable for at least the reasons discussed with respect to independent claim 46. Consequently, Applicants request that the Board reverse the Examiner’s rejection of dependent claims 47, 49, and 51-53.

Dependent claim 48

Dependent claim 48 depends from independent claim 46 and recites, “[t]he stent of claim 46 wherein the tubular, serpentine segment is self-expandable.” When read in conjunction with claim 46, claim 48 recites that the serpentine segment is self-expandable; therefore, the coil segment is balloon expandable.

As discussed above with respect to claim 55, one of ordinary skill in the art would not be motivated to make the Examiner’s alleged modification. The stent of Hojeibane, which is designed to be used with a thin and highly elastic coating that does “not interfere with the desired expansion of the stent,” would not be used with the sleeve element 36 of Vonesh, which limits expansion of the stent. *See* MPEP § 2143.01(V) (“If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.” (citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984))). Consequently, Applicants request that the Board reverse the Examiner’s rejection of dependent claim 48 for this additional reason.

Issue 2: The combination of Imran (US 5,817,126) in view of Vonesh (US 6,336,937), Hojeibane (US 5,911,732), and Klein (US5,593,442) does not render claims 43, 45, and 50 obvious under 35 USC § 103(a).

Dependent claims 43, 45, and 50

Claims 43 and 45 depend either directly or indirectly from independent claim 38 while claim 50 depends from claim 46. The addition of Klein does not remedy the deficiencies of Imran, Vonesh, and Hojeibane, as discussed above with respect to independent claims 38 and 46. Consequently, Applicants request that the Board reverse the Examiner's rejection of dependent claims 43, 45, and 50.

CONCLUSION

Based on at least the foregoing arguments, Applicants respectfully submit that the rejections presented by the Examiner fail to render obvious Applicants' claims. Accordingly, Applicants respectfully request that the Board reverse the Examiner's rejections.

Respectfully submitted,

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Date: February 1, 2010

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(viii) Claims Appendix

Claim 38. A stent having a longitudinal axis comprising a plurality of segments, including at least one coil segment connected to at least one serpentine segment, the at least one serpentine segment forming an annular ring about the longitudinal axis of the stent, the at least one coil segment having curved portions that extend at least 90 degrees about the longitudinal axis, adjacent portions which are aligned in a circumferential direction and longitudinally offset from one another having a substantially constant longitudinal distance between each other, each of the at least one coil segments extending along a greater longitudinal distance than each of the at least one serpentine segments, wherein either the coil segment is balloon expandable and not self-expanding and the serpentine segment is self-expanding and not balloon expandable, or the coil segment is self-expanding and not balloon expandable and the serpentine segment is balloon expandable and not self-expanding.

Claim 39. The stent of claim 38 having a first end segment and a second end segment, wherein each of the first and second end segments is an expandable serpentine segment.

Claim 40. The stent of claim 39 comprising only one segment which is in the form of a coil and which connects the first and second end segments.

Claim 41. The stent of claim 40 wherein the first and second end segments are self-expandable.

Claim 43. The stent of claim 41 wherein the first and second end segments are made of spring steel.

Claim 44. The stent of claim 40 wherein the first and second end segments are balloon expandable.

Claim 45. The stent of claim 38 wherein the segment which is in the form of a coil is made of spring steel.

Claim 46. A stent comprising a coil segment and a tubular, serpentine segment, the coil segment being longer than the tubular serpentine segment in a longitudinal direction, the coil segment having curved portions that extend at least 90 degrees about the longitudinal axis, adjacent portions which are aligned in a circumferential direction and longitudinally offset from one another having a substantially constant distance between each other, wherein either the coil segment is balloon expandable and not self-expanding and the serpentine segment is self-expanding and not balloon expandable, or the coil segment is self-expanding and not balloon expandable and the serpentine segment is balloon expandable and not self-expanding.

Claim 47. The stent of claim 46 wherein the tubular, serpentine segment is balloon expandable.

Claim 48. The stent of claim 46 wherein the tubular, serpentine segment is self-expandable.

Claim 49. The stent of claim 46 having a first end and a second end, the first end being a tubular, serpentine segment and the second end being a tubular, serpentine segment.

Claim 50. The stent of claim 46 where the coil segment is made of spring steel.

Claim 51. The stent of claim 46 wherein the coil segment has an outer diameter of no more than 6 mm when deployed.

Claim 52. The stent of claim 51 having an outer diameter of no more than 6 mm when deployed.

Claim 53. The stent of claim 51 having a length of no more than 20 mm.

Claim 54. The stent of claim 38, wherein at least one coil segment is expandable by self-expansion and at least one serpentine segment is expandable by balloon expansion.

Claim 55. The stent of claim 38, wherein at least one coil segment is expandable by balloon-expansion and at least one serpentine segment is expandable by self-expansion.

(ix) Evidence Appendix

(x) Related Proceedings Appendix